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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,508	12/03/2003	Akio Kawamura	SUGIY0004	5017
24203	7590	06/22/2006	EXAMINER CHAPMAN, GINGER T	
GRIFFIN & SZIPL, PC SUITE PH-1 2300 NINTH STREET, SOUTH ARLINGTON, VA 22204			ART UNIT 3761	
PAPER NUMBER				

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/725,508

Applicant(s)

KAWAMURA, AKIO

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/03/2003</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

## DETAILED ACTION

### *Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “**56a**” has been used to designate both “**projection**” and “**ring**”. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character not mentioned in the description: **56b**. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

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applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colone (US 4,822,341) in view of Kawamura (EP 1013293).

With regard to claim 1, as seen in Figures 2A, 2B, 4 Colone discloses a no-needle blood access device for hemodialysis (10) comprising an elongated body (20) provided at its upper surface (28) with a recess (26), a periphery of the recess being formed with a peripheral wall (34) defining a well therein (30); shutter (24) slidably housed at the upper part of the body (20) so that the lower surface (32) is flush with the bottom surface of the recess (30) the shutter (24) including through holes (58, 60); a longitudinally extending through-hole (26) disposed in the lower part of the body (20), each of first and second artificial conduits (fig. 7: 92, 94) fitted into respective ends of the longitudinally extending through-hole (26), the conduits (92, 94) anastomosed to a targeted artery or vein (fig. 6); and a pair of vertical through holes (48, 50) disposed at portions of the body (20) each communicating to the respective through-holes (58, 60) of the shutter (22) when opened; the well (30) is in communication with each of the artificial conduits (92, 94) through the longitudinally extending through hole (26) and the vertical through holes (48, 50) of the body (20), and when the shutter is slid the well (30) is out of communication with each of the artificial conduits (92, 94).

Colone discloses an elongated body of rigid material but does not expressly disclose the body is metallic. Kawamura, at c. 4, ll. 45-55 teaches the ability of a metallic body to be light and biocompatible thus expressing the desire for such a metallic body. As best depicted in Figure 1, Akio teaches the device (10) having a metallic body (20). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the body of Colone metallic as taught by Kawamura thereby providing a light biocompatible

device for implanting since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. *In re Leshin*, 125 USPQ 416.

Colone discloses the shutter functions to open and close the through-holes when slid within the pocket but does not disclose a pair of shutters. As best depicted in Figure 2, Kawamura discloses a pair of shutters (34, 36) slideable within pockets (38, 40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the shutter of Colone as two shutters since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either one shutter or two shutters sliding to open and close the through-holes because the shutters of Colone and Kawamura perform the same function of opening and closing the through-holes.

With regard to claim 2, Kawamura discloses in Figure 2 each of the shutters (34, 36) including a horizontal portion (22) housed within the pocket (38, 40) and a vertical portion formed in the end facing with respect to each other (fig. 2) each of the through-holes (of the shutters

With regard to claims 2 and 3, as seen in Figures 1 and 2A, Colone discloses the shutter (22) including a horizontal portion (32) housed within the pocket (30) and a vertical portion (56) the through-hole (60) of the shutter provided at the vertical portion, and the vertical portion (56) is used when the shutter is opened and closed (c. 6, l. 20-21). Colone discloses the invention substantially as claimed except for duplicating the shutter. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to use one shutter for each through-hole since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

With regard to claims 4-6, Colone discloses a cannula assembly (fig. 4) connected to a dialyzer (88), including a pair of cannulas (46, 80), one end (44) provided with an adapter (36) for mounting the cannula to the body (20), the adapter provided with a locking member (42) for preventing the cannula from being removed.

With regard to claims 7-9, the combination of Colone and Kawamura disclose in Kawamura '239 Figure 3A, the locking member (42, 44) includes a projection (36a) for locking in a groove (34a) formed in a side surface (fig. 3A) of the vertical portion of the shutter (34).

With regard to claims 10-12, the combination of Colone and Kawamura disclose in Kawamura '239 Figure 3B, the locking member (42, 44) includes a groove (36b) for locking in a projection (34b) formed in a side surface (fig. 3A) of the vertical portion of the shutter (36).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,231,541 issued to Kawamura discloses in figures 1 and 2 a no-needle blood access device having two slideable shutters (34, 36).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 8:30 a.m. to 5:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman  
Examiner, Art Unit 3761  
06/01/06

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TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

